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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/781,357      | 02/17/2004  | Anant V. Hegde       | PAVA-002/01US       | 9201             |

23419 7590 08/11/2006

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| EXAMINER |
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HOLMES, REX R

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| ART UNIT | PAPER NUMBER |
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3762

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/781,357

Applicant(s)

HEGDE ET AL

Examiner

Rex Holmes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-197 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-197 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-49 are drawn to device for engaging a 2 layer lumen, classified in class 604, subclass 43.
  - II. Claims 50-85 are drawn to a system for compressing a lumen comprising a cuff, classified in class 604, subclass 90.
  - III. Claims 86-99 are drawn to a method for augmenting flow through a lumen, classified in class 604, subclass 99.02.
  - IV. Claims 100-116 are drawn to a method for augmenting flow through a lumen without detecting a cardiac trigger, classified in class 604, subclass 164.02.
  - V. Claims 117-133 are drawn to a system for compressing a lumen with a multi-layer cuff, classified in class 604, subclass 524.
  - VI. Claims 134-181 are drawn to system to compress a lumen with a cuff utilizing an electroactive polymer pump, classified in class 604, subclass 250.
  - VII. Claims 182-195 are drawn to a method for augmenting blood flow based on sensing an event, classified in class 604, subclass 513.
  - VIII. Claim 196 is drawn to a method for forming a stacked electrode, classified in class 29, subclass 746.

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IX. Claim 197 is drawn to a system to augment blood flow, classified in class 600, subclass 466.

2. Inventions III-IV, VII and I-II, V-VI, IX are related as process and apparatus. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case Invention III requires that the cardiac trigger and cardiac cycle while none of the apparatus's I-II, V-VI or IX require a cardiac trigger or even have to be used with living organisms, the apparatuses can all be used synchronously without a trigger. Invention IV requires the deforming of a vessel while none of the apparatus's I-II, V-VI or IX require that the lumen be a vessel or connected to a vessel, they could be used with standard medical grade tubing to control the flow of fluids. Invention VII requires the sensing of an R-wave while none of apparatus's I-II, V-VI or IX require a cardiac trigger or even have to be used with living organisms, the apparatuses can all be used synchronously without a trigger.

3. Inventions VIII and III-IV, VII, I-II, V-VI, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are a method for forming a stacked electrode and a method and apparatus for augmenting blood flow.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Combination I does not need the use of a cuff or an electroactive polymer pump while the subcombination requires the use of a cuff and an electroactive polymer pump. The subcombination has separate utility such as compressing a lumen, while the combination only engages a lumen.

4. Inventions I and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Combination 1 does not require a compliant layer and a semi-compliant layer and an electroactive diaphragm pump that expands the compliant layer. The subcombination has separate utility such as not encircling a body lumen, while the combination requires a length sufficient to at least partially encircle a body lumen.

5. Inventions II and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and

(2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the use of a conduit connecting the output and the cavity. The subcombination has separate utility such as expanding the expandable layer at random times, based on any cues, while the combination requires that the polymer pump expand the expandable layer in synchronization with a portion of a cardiac cycle.

6. Inventions I and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the use of a controller or a polymer pump. The subcombination has separate utility such as not encircling a body lumen, while the combination requires a length sufficient to at least partially encircle a body lumen.

7. Inventions II and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require

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the use of a controller or a conduit connected to the polymer pump. The subcombination has separate utility such as expanding the expandable layer at random times, based on any cues, while the combination requires that the polymer pump expand the expandable layer in synchronization with a portion of a cardiac cycle.

8. Inventions V and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the use of a controller. The subcombination has separate utility such as having two compliant layers as the second layer has to be stiffer than the first but the stiffness does not have to be so great as to make it semi-compliant, unlike the second layer of the combination that requires that it be semi-compliant.

9. Inventions I and IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require an impeller assist device. The subcombination has separate utility such as not having to have a first or second layer, while the combination requires a first and a second layer.

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10. Inventions II and IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require an impeller assist device. The subcombination has separate utility such as it does not require a cuff, thus it can use an impeller or a solenoid to augment blood without having to expand a lumen.

11. Inventions V and IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require an impeller assist device. The subcombination has separate utility such as it does not require a cuff, thus it can use an impeller or a solenoid to augment blood without having to expand a lumen.

12. Inventions VI and IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP §



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806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require an impeller assist device. The subcombination has separate utility such as it does not require a cuff or a controller that receives signals based on the cardiac cycle, thus it can use an impeller or a solenoid to augment blood without having to expand a lumen at any interval or based on an external cue.

13. Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination III does not require the deformation of vessel wall. The subcombination has separate utility such as compressing vessels to limit flow instead of augment it.

14. Inventions III and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the computing of a cardiac interval. The subcombination has separate utility such as not requiring the deformation of at least a portion of the body lumen via a pumped fluid,

instead the subcombination does not require the pumping of a fluid, it could be used to move a solid actuated arm.

15. Inventions IV and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a sensing event. The subcombination has separate utility not requiring the enlargement of a cavity, the subcombination could be used to actually shrink a cavity and thus reduce flow.

16. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

17. This application contains claims directed to the following patentably distinct species: AN EMBODIMENT (SPECIES) MUST BE CHOSEN FROM EACH OF THE LISTED GROUPS BELOW.

18. Group A, Embodiments 1-3 represented by the different types of electroactive polymers: Embodiment 1, represented by a dielectric electrostrictive electroactive polymer, Embodiment 2, represented by a ion exchange polymer metal composite,

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Embodiment 3, represented by an anode surface, a cathode surface, and an elastomer material.

Group B, Embodiments 4-11 represented by the different types of body lumens: Embodiment 4, represented by the ascending aorta, Embodiment 5, represented by the descending aorta, Embodiment 6, represented by the a set of intercostals arteries, Embodiment 7, represented by a set of intercostals veins, Embodiment 8, represented by the superior vena cave, Embodiment 9, represented by inferior vena cave, Embodiment 10, represented by the pulmonary vein, Embodiment 11, represented by the pulmonary artery.

Group C, Embodiments 12-18 represented by the different types of mating fasteners and how they are attached: Embodiment 12, represented by magnets, Embodiment 13, represented by at least one being a magnet, Embodiment 14, represented by opposite sides of a buckle, Embodiment 15, represented by a screw and a screw receiving material, Embodiment 16, represented by a hook and loop, Embodiment 17, represented by a locking ring, Embodiment 18, represented by a positive-lock.

Group D, Embodiments 19 and 20 represented by the different types of controller actuation results: Embodiment 19 represented by copulsation of a portion of the cardiac cycle, Embodiment 20 represented by counterpulsation of a portion of the cardiac cycle.

Group E, Embodiments 21 and 22 represented by the different types of cuff sizes: Embodiment 21 represented by the cuff sized to partially encircle the lumen, Embodiment 22, represented by the cuff sized to fully encircle the lumen.

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Group F, Embodiments 23 - 25 represented by the different types of electroactive pump designs/types: Embodiment 23, represents a single chamber, Embodiment 24, represents more than one chamber.

Group G, Embodiments 25 - 30 represented by the different types of cardiac triggers/cycles: Embodiment 25 represented by R wave, Embodiment 26, represented by ventricular systole, Embodiment 27, represented by aortic pressure, Embodiment 28, represented by Q-T interval, Embodiment 29, represented by T-wave Embodiment 30, represented by diastole.

Group H, Embodiments 31 and 32 represented by the different types of electroactive polymers are how they are actuated: Embodiment 31, represented by the lever arms moving together, Embodiment 32, represented by the lever arms moving apart.

Group I, Embodiments 33-35 represented by the different types of bias elements: Embodiment 33, represents a foam material, Embodiment 34, represents a spring, Embodiment 345, represents a fluid.

Group J, Embodiments 36-37 represented by the different types of body pressures: Embodiment 36, represents venous pressure, Embodiment 37, represents arterial pressure.

Group K, Embodiments 38-39 represented by the different types of polymer pumps: Embodiment 38, represented by a rolled polymer pump, Embodiment 39, represented by "c" ring polymer pump.

Group L, Embodiments 40-41 represented by the different types of triggers:  
Embodiment 40, represented by an R-wave sensing polymer pump, Embodiment 41, represented by a pressure sensing polymer pump.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are allowable and generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.  
MPEP § 809.02(a).

19. A telephone call was made to Cliff Liu (650) 843-5000 on 08/07/06 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

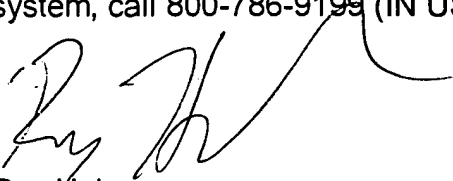
20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rex Holmes



George Evanisko

Primary Examiner

9/7/6